

REMARKS

Amendments to the Claims

Claim 105

Claim 105 has been amended to include the limitation that the method is directed to selecting a dose of an anti-oxidant compound for administration to a human. Claim 105 has also been amended to include the limitations (i) that the polymorphism in the catalase gene is manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262, and (ii) that the polymorphism in the superoxide dismutase gene to be selected from a group of four specifically claimed polymorphisms; namely a) a change from an alanine residue to a valine residue at amino acid residue 9 of MnSOD, b) a change from an isoleucine residue to a thymine residue at amino acid residue 58 of MnSOD, c) a change from a valine residue to a glutamic acid residue at amino acid residue 7 of CZSOD, and d) a change from a cysteine residue to a phenylalanine residue at amino acid residue 6 of CZSOD. Support for the amendments to Claim 105 can be found throughout the specification as originally filed, specifically including without limitation (i) page 11, at ¶40; and (ii) cancelled claim 39. The recitation that “the method assesses a relative susceptibility of the human to oxidative damage” has been deleted from the language of claim 105. Additional amendments to claim 105 are grammatical in nature. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 105, as presently amended, is now pending.

Claim 110

Claim 110 has been amended to include the limitations of amended claim 105 and to remove relative terms. Claim 110 has also been amended to correct an obvious typographical error. Support for the amendments to Claim 110 can be found throughout the specification as originally filed, specifically including without limitation page 3, at ¶6; and page 11, at ¶ 40. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 110, as presently amended, is now pending.

Claim 111

Claim 111 has been amended to include the limitation (i) that the polymorphism in the catalase gene is manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262, and (ii) that the polymorphism in the superoxide dismutase gene to be selected from a group of four specifically claimed polymorphisms; namely a) a change from an alanine residue to a valine residue at amino acid residue 9 of MnSOD, b) a change from an isoleucine residue to a thymine residue at amino acid residue 58 of MnSOD, c) a change from a valine residue to a glutamic acid residue at amino acid residue 7 of CZSOD, and d) a change from a cysteine residue to a phenylalanine residue at amino acid residue 6 of CZSOD. Claim 111 has also been amended to remove the language “or an increased dose of an antioxidant composition,” as that language was found objectionable as indefinite by the Examiner. Additional amendments to claim 111 are grammatical in nature. Support for the amendments to Claim 111 can be found throughout the specification as originally filed, specifically including without limitation (i) page 3, at ¶6; page 11, at ¶ 40; and, (ii) cancelled claim

39. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 111, as presently amended, is now pending.

Claim 112

Claim 112 has been amended to include the limitations of claim 105. Support for the amendments to Claim 112 can be found throughout the specification as originally filed, specifically including without limitation (i) page 3, at ¶6; page 11, at ¶ 40; and, (ii) cancelled claim 39. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 112, as presently amended, is now pending.

Summary of Now-Pending Claims

In light of the foregoing, Claims 105, and 110–112 are now pending in this application following entry of this amendment. Applicant respectfully submits that the now-pending claims are in condition for allowance.

Election / Restrictions

The elected invention is “methods for selecting a dose of an anti-oxidant by assaying for a polymorphism in each of a SOD gene and a catalase gene.” (*See*, the Examiner’s 6/3/05 Non-Final Office Action, at pg. 2). The Examiner properly notes that, in the response filed by Applicants on 11/1/02, Applicant elected without traverse the invention of Group II pursuant to the Examiner’s 10/2/02 restriction requirement. Further to that election, the Examiner, during continued examination, made a restriction requirement dated 9/1/04 wherein the Applicants were required to elect a specific combination of polymorphisms. Applicants filed an amendment in response to the

aforementioned restriction requirement on 3/3/05 wherein the Applicants elected with traverse the aforementioned methods for selecting a dose of an anti-oxidant compound **by assaying for certain polymorphisms in a superoxide dismutase gene and a catalase gene**. The Examiner explains that the 9/1/2004 restriction requirement “allowed for the election of a particular combination of polymorphisms.” (*See*, the Examiner’s 6/3/05 Non-Final Office Action, at pg. 2).

The Applicants thank the Examiner for examination of claim 105 (prior to the present amendment thereof) for its full scope. (*See*, the Examiner’s 6/3/05 Non-Final Office Action, at pg. 5). The Applicants respectfully submit that the claims recite a method for selecting a dose of anti-oxidant composition for administration to a human by assessing a limited number of polymorphisms in two (2) genes, specifically, a superoxide dismutase gene and a catalase gene, congruent with the Applicants’ 3/3/05 election in connection with the Examiner’s 9/1/04 restriction requirement. Accordingly, Applicants contend that examination of the now-pending claims does not create undue hardship on the Examiner and the same are within the scope of the Examiner’s 9/1/2004 restriction requirement.

Claim Rejections – 35 U.S.C. § 112, ¶ 1

The Examiner rejected claim 105 (prior to the present amendment thereof) under 35 U.S.C. § 112, ¶ 1, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the claim “contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art...to make and/or use the invention.” (See, the Examiner’s 6/3/05 Non-Final Office Action, at pg. 5).

The Applicants submit that the Examiner has assigned a far greater weight to the preamble of claim 105 (namely, “[a] method of selecting a dose of anti-oxidant composition for administration to a human”) than is just. The preamble (in the instant case, “[a] method of selecting a dose of an anti-oxidant composition for administration to a human”) should not be construed as a limitation on the claim itself. To determine the amount of import that should be ascribed to the preamble, the Examiner should consider the claim as a whole. See, *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999), citing, *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)(where “the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention’s limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to the claim construction because it cannot be said to constitute or explain a claim limitation.”). The Applicants have set forth a structurally complete invention in the body of amended claim 105 such that the preamble merely states a purpose or intended use for the invention. *Rowe*, 112 F.3d at 478. Specifically, the dose of anti-oxidant composition is determined by assessing an occurrence in a human’s genome of a quantity of oxidative damage-associated polymorphisms. (See, the Specification-as-Filed, pg. 3, at ¶6). Furthermore, the Applicants do not rely on the preamble of claim 105 (as amended) to distinguish their invention over the prior art and, therefore, it does not affect the structure or steps of the

claimed invention (i.e., assessing an occurrence in a human's genome of oxidative damage-associated polymorphisms to indicate an increased susceptibility of the human to a pathology involving oxidative damage for the purpose of selecting a dose of anti-oxidant composition for administration to the human). *See, IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2002); *STX, LLC v. Brine, Inc.*, 211 F.3d 588, 591 (Fed. Cir. 2000)(preamble language merely extolling benefits or features of the claimed invention does not limit the scope without clear reliance on those benefits or features as patentably significant).

The Examiner cites the factors in *In re Wands*, 858 F.2d 731, 8 USPQ 1400 (Fed. Cir. 1988) as grounds for rejecting claim 105 under 35 U.S.C. §112, ¶1. The *Wands* factors cited by the Examiner are discussed herein below in light of the present amendment. It is noted that the *Wands* factors must be considered as a whole after weighing all of the factual issues set forth therein. *Id.*, 858 F.2d at 737.

Breadth of the Claims

The Examiner contends that claims are “broadly drawn to a method of selecting a dose of anti-oxidant composition for administration to a human wherein the method comprises assessing the occurrence of **any** disorder-associated polymorphism in **any** superoxide dismutase gene or catalase gene...”(Emphasis added.)(*See*, the Examiner's 6/3/05 Non-Final Office Action, at pg. 6). Based on this characterization of the invention, the Examiner maintains that claim 105 (prior to the present amendment) encompasses no less than 441 polymorphisms which may be assayed for and/or assessed to select a dose of anti-oxidant composition for administration to a human.

By the present amendment, the claims are drawn on the elected invention whereby the selection of a dose of anti-oxidant composition for administration to a human is indicated by assessment of a limited a quantity of specifically claimed oxidative damage-associated polymorphisms. The Applicants' invention is a suitable estimate or indicator (for the purpose of formulating anti-oxidant compositions) of an individual's susceptibility to oxidative stress which can be made simply by assessing several relevant genes. (*See*, the Applicants' 6/2/03 Amendment, at pg. 24). The Examiner contends that the "claims include the detection of any of a multitude of polymorphisms that are in some manner associated with any disease..., [but] do not specify the particular polymorphism[s]." To that end, the relevant nucleotide position and identity of the polymorphisms are now clearly claimed by the present amendment and the Applicants now assert that the breadth of the claims is narrow (in fact encompassing only a small, but important, aspect of the Applicants' invention). (*See*, the Examiner's 9/1/04 Restriction Requirement wherein the elected invention is determined to be patentably distinct over other embodiments of the invention which may be claimed in this or another patent application). Thus, the *Wands* consideration relating to the breadth of the claims now favors a finding of enablement in the instant case.

Nature of the Invention

As the Examiner points out, the present invention falls within a class of inventions characterized as "the unpredictable arts such as chemistry and biology." *See, Mycolgen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001). However, the level of skill in the art is high. Therefore, a method for formulating anti-oxidant

compositions to supplement the body's normal anti-oxidant mechanisms which relies on assessment of a limited number of polymorphisms in a human's genome is firmly within the level of skill in the art. Moreover, Applicants aver that their invention is narrowly drawn to specific nucleotide variations in a human's genome that predict susceptibility to oxidative stress in such a way that an anti-oxidant composition can be (or the advisability that an anti-oxidant composition should be) administered to the human will be appreciated by one skilled in the art.

It should be noted that the Applicants have not simply discovered that several specific genetic polymorphisms are associated with the susceptibility of a human to oxidative stress. Instead, the Applicants have made the much broader discovery that a human's susceptibility to oxidative stress is affected by occurrence of certain genetic polymorphisms (which may or may not be correlated with a disorder, including disorders not necessarily related to oxidative stress). Restated, a polymorphism in any one of the relevant genes is sufficiently detrimental to be manifested (even in only some humans) as a disorder is sufficient to increase the susceptibility of the human to oxidative stress. Thus, by practicing the claimed invention (i.e., analyzing occurrence in a human's genome of these detrimental polymorphisms), one skilled in the art can estimate the susceptibility of that human to oxidative damage and select an appropriate dose of an anti-oxidant composition to administer to the human. (*See*, the Applicants' 6/2/03 Amendment, at pg. 17; R.Ricciardi's 4/30/07 Declaration, pg. 2, at ¶7).

Teachings in the Specification and State of the Art

The Examiner correctly notes that the specification teaches a method for determining a dose of an anti-oxidant composition for administration to a human by assessing the occurrence of a specific combination of disorder-associated polymorphisms in a human's genome. (*See, also*, the Specification-as-Filed, pg. 3, at ¶6).

The Examiner concentrates so intently on dosage measurements of an eventual anti-oxidant composition that the nature of the invention is not appreciated. The invention relates to the administration of an anti-oxidant composition to a human that exhibits overall global susceptibility to oxidative stress as determined by the assessment of the claimed polymorphisms. (*See*, the Specification-as-Filed, pg. 10, at ¶35). If the individual's genome includes a form of one or more of the claimed polymorphisms, then that indicates that the function of the gene is impaired (wholly or partially) and that the individual is more susceptible to oxidative stress than an individual whose genome does not include the disorder-associated form of the gene. Accordingly, it is then advisable (as will be appreciated by one skilled in the art) that the individual whose genome does include one or more of the claimed polymorphisms be administered an anti-oxidant composition. (*See*, the Specification-as-Filed, pg. 3, at ¶ 8, pg. 5, ¶11, pg. 13, ¶42; R.Ricciardi's 4/30/07 Declaration, pg. 2, at ¶ 7).

Working Examples

The Applicants respectfully submit that the disclosure of a working example or reduction to practice is not a prerequisite to invention. *See, Burroughs Wellcome Co. v. Barr Labs, Inc.*, 40 F.3d 1223 (Fed. Cir. 1994). "The filing of a patent application serves

as conception and constructive reduction to practice of the subject matter described in the application. Thus the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application.” *See*, MPEP §2138.05, *citing*, *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998). Applicants respectfully submit that the specification-as-filed in this case provides sufficient disclosure under the “how to use” and “how to make” mandates of 35 U.S.C. §112, ¶1. *See*, *Id.*, *citing*, *Kawai v. Metlesics*, 480 F.2d 880, 886 (CCPA 1973)(stating that a constructive reduction to practice is proven when the specification discloses a practical utility where one would not otherwise be obvious). *See, also*, MPEP § 2164.04(“Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether a working example is disclosed.”).

Notwithstanding the foregoing, the Applicants state that specification teaches a method of selecting a dose of anti-oxidant composition which “comprises assessing occurrence in the human’s genome of disorder-associated polymorphisms” which, once identified, will direct one skilled in the art “to supplement the body’s normal anti-oxidant mechanisms” with appropriate anti-oxidant compositions. (*See*, the Specification-as-Filed, pg. 5, at ¶11, pg. 13, at ¶42). Therefore, methods in which the dosage of an antioxidant composition may be selected by assaying for the claimed polymorphisms to assess the overall state of oxidative stress to which a human is subjected are disclosed, thus enabling the full scope of the claimed invention. (*See*, the Specification-as-Filed, pg. 13, at ¶42).

Moreover, for the reasons discussed in this amendment, the Applicants respectfully contend that skilled artisans can practice the claimed methods without studying working examples. Accordingly, the lack of a working example cannot stand as a basis for non-enablement.

The Predictability or Unpredictability of the Art and Degree of Experimentation

Appropriate amounts of an anti-oxidant composition for administration to normal humans (i.e., humans who do not exhibit unusual susceptibility to oxidative stress) are known. For example, the Examiner cites the recommended daily allowance (RDA) for known appropriate measures of anti-oxidant compositions. (*See*, the Examiner's 6/3/05 Non-Final Office Action, at pg. 10). It would be immediately apparent to one skilled in the art to increase the amount of anti-oxidant composition in individuals who are found to have heightened susceptibility to oxidative stress. (*See*, the Specification-as-Filed, at pg. 5, at ¶11). For the reasons set forth herein, the Applicants respectfully contend that substantially no experimentation is necessary to practice the claimed methods throughout the full scope of what is claimed and that the specification adequately enables the claimed invention for that reason.

Finally, the Examiner cites the Forsberg article (Forsberg, *et al.*, 2001, Arch. Biochem. Biophys. 389(1): 84-93) for the proposition that correlating occurrence of a polymorphism with a phenotypic consequence is difficult and unpredictable. Although the Applicants do not concede this point has any bearing on the present invention or enablement of the present invention, the Applicants respectfully disagree with the Examiner's position in this regard. The Applicants have directed the Examiner to a

number of ready resources which correlate polymorphisms with phenotypic expressions. (See, R. Ricciardi's 4/30/04 Declaration, pg, 2, at ¶¶7-9).

The Forsberg article serves illustrate the significance of the Applicants' invention. The Applicants have made the important discovery that it is not necessary to thoroughly understand the causative link between the occurrence of a polymorphism and a corresponding phenotypic expression. Instead, the Applicants have discovered a solution to the problem of assessing an individual's susceptibility to oxidative stress for the purpose of formulating an anti-oxidant composition.

The present invention demonstrates that the prior art lost the forest for the trees. The present invention details how specific polymorphisms in a human's genome are informative with regard to that human's susceptibility to oxidative stress (in a way that may or may not exert a phenotypic effect, but may provide direction in the prediction of a phenotypic effect) in a simple, readily-assessable way such that an anti-oxidant composition appropriate for that human can be selected by one skilled in the art. The prior art simply did not appreciate the Applicants' elegantly simply methods, as indicated by the Examiner's failure to find any anticipatory or obviating references.

Among enzymes that catalyze the conversion of a toxic oxygen species to a less toxic oxygen species, four are of particular relevance, namely mitochondrial manganese superoxide dismutase (MnSOD), cytoplasmic copper/zinc superoxide dismutase (CZSOD), catalase (CAT), and glutathione peroxidase (GP). Polymorphisms that occur in these genes are known to be associated with various disorders. (See, e.g., Kimura et al., 2000 Am. J. Ophthalmol. 130:769-773). (See, the Specification-as-Filed, pg. 9, at ¶34).

It was not previously appreciated in the prior art, however, that the detection in a human's genome of two or more disorder-associated polymorphisms in genes associated with oxidative stress is indicative that the human globally exhibits enhanced susceptibility to oxidative damage. (*See*, the Specification-as-Filed, pg. 10, at ¶35). Thus, the present invention assesses the human's global susceptibility to oxidative damage which, in turn, teaches one skilled in the art to select a dose of anti-oxidant composition for administration to the human.

Moreover, contrary to the Examiner's inference, the Applicants do not claim administration of a dose of anti-oxidant to a human for "the treatment or prevention of a disease relative to the number of polymorphisms" detected in the human. (*See*, the Examiner's 6/3/05 Non-Final Office Action, at pg. 10). Rather, the Applicants claim a method of selecting a dose of an anti-oxidant composition for administration to a human by assessing the overall state of oxidative stress to which a human is subjected based on an assay for specific polymorphisms to supplement the body's normal anti-oxidant mechanisms. (*See*, the Specification-as-Filed, pg. 3, at ¶6; pg. 5, at ¶11). This invention is readily appreciated by one skilled in the art such that the claims are enabled throughout their full scope.

Amount of Direction or Guidance Provided by the Specification

The specification clearly teaches a method of selecting a dose of an anti-oxidant composition to a human by assessing the occurrence in that human's genome of a quantity of oxidative damage-associated polymorphisms. Quantitative assessment of the claimed polymorphisms permits evaluation of the risks and benefits of a variety of anti-

oxidant compositions for administration. (*See*, the Specification-as-Filed, pg. 5, at ¶11; p. 11, at ¶40; p. 13, ¶41).

As noted above, it was not previously appreciated that detection in a human's genome of two or more disorder-associated polymorphisms in genes associated with oxidative stress is indicative that the human globally exhibits enhanced susceptibility to oxidative damage. Previous studies are believed to have recognized only association between a polymorphism in one of these genes and a particular disorder. (*See*, the Specification-as -Filed, pg. 10, at ¶35). Thus, the invention assesses a human's global susceptibility to oxidative damage such that an appropriate dose of an anti-oxidant composition can be administered to the human by one skilled in the art. (*Id.*).

The Examiner alleges, relative to the *Wands* consideration of the amount of direction or guidance provided by the specification, that the specification has not established "a baseline dosage and does not teach what degree of increase in an antioxidant would be required for each polymorphism" and does not provide sufficient guidance as to how to select an appropriate "increased dose" of antioxidant. (*See*, the Examiner's 6/3/05 Non-Final Office Action, at pg. 11). The Examiner therefore concludes "that there are no teachings in the specification regarding the effect of increasing the dosage of an antioxidant based on the total number of polymorphisms present in an individual's SOD and catalase genes on the treatment outcome or prevention of a disease. (*Id.*, at pg. 12). In the next breath, however, the Examiner states that it is known that, "mutations in antioxidant enzymes increase susceptibility to disease and that a diet rich in antioxidants decreases susceptibility to disease were known in the

art at the time the invention was made.” (Id.; *see, also*, Ambrosone, C., et al., 1999 Cancer Research 59:602-606). Furthermore, as more fully discussed later in this section, the Examiner finds the language “an increased dose of an anti-oxidant” objectionable. To that end, the Applicants respectfully state that language has been deleted from the claims by the present amendment.

The relative susceptibility of a human to oxidative damage is the indicator by which an appropriate dose of an anti-oxidant composition is determined, this is appreciated by one of skill in the art. (*See*, the Specification-as-Filed, pg. 13, ¶42). Accordingly, it is appropriate to restate the nature of the Applicants’ invention. The Applicants’ claimed invention is a method for the purpose of formulating anti-oxidant compositions determined by an individual’s overall susceptibility to oxidative stress through assessment of a limited number polymorphisms in a limited number of relevant genes.

Regarding selecting a dose of anti-oxidant composition for administration, the Applicants maintain that the claims recite that the human is being treated with or is a candidate for treatment with an anti-oxidant composition based on the detection of the claimed polymorphisms which exhibit the human’s global susceptibility to oxidative stress. Accordingly, as recited in the amended claims, an appropriate course of therapy is determined for only those pathologies (whether or not phenotypically exhibited by the individual) involving oxidative damage for which a human is being treated with, or is a candidate for treatment with an anti-oxidant composition as determined by the assessment of the relevant genes in the manner claimed.

The Examiner states that “the present invention is not limited to methods of determining whether to administer an antioxidant to a patient based on the presence of a mutation in a SOD or CAT gene. Rather, the claims require determining an appropriate increase in dosage of an antioxidant, where the dosage is increased based on each occurrence of any disorder polymorphism in a SOD or CAT gene.” (*See*, the Examiner’s 6/3/05 Non-Final Office Action, at pgs. 12-13). The Applicants state that by the present amendment, the claims no longer encompass “determining an appropriate increase in dosage of anti-oxidant” based on any disorder polymorphism in a SOD or CAT gene. Accordingly, the Applicants request withdrawal of the rejection of the claims under 35 U.S.C. §112, ¶1 for the reason that the claimed invention is fully enabled by the specification as filed in this case.

Claim Rejection – 35 U.S.C. § 112, ¶ 2

Claim 105 was rejected by the Examiner as indefinite under 35 U.S.C. §112, ¶2 over the relative term “increased dose.” By the present amendment, the allegedly relative term is deleted and the rejection rendered moot. Thus, the Applicants respectfully request that the rejection pursuant to 35 U.S.C. §112, ¶2 be withdrawn and the claims allowed.

Without acquiescing in the present grounds for rejection, by this amendment and the remarks contained herein, the now-pending claims recite methods for selecting a dose of anti-oxidant in a human subject by assessing a limited number of polymorphisms in a limited number of genes. Applicants respectfully submit that the claims are, therefore,

clearly drawn on the elected invention. Thus, Applicants believe that the Examiner's present grounds for rejection have been obviated and respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. §112, ¶¶1-2.

No Disclaimers or Disavowals Are Contained Herein

Although the present communication may include alterations to the application or claims, or characterizations of the claim scope or referenced art, the Applicants do not concede in this application that the previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made merely to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any of the previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

It is respectfully submitted that each of the presently pending claims (105, 110-112) is in condition for allowance and notification to that effect is requested. Further, Applicants respectfully submit that each of the outstanding rejections have been

addressed herein and resolved such that the pending claims are in condition for allowance.

The undersigned has made a good faith effort to respond to and overcome all of the rejections in this case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact Applicants' undersigned representative if it is believed that prosecution of this application may be assisted thereby. Although only certain arguments regarding patentability are set forth herein, there may be other arguments and reasons why the claimed invention is patentable. Applicants reserve the right to raise these arguments in the future.

The fees believed to be due, if any, have been paid at the time of filing this communication.

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Respectfully submitted,
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